

5. 510(k) SUMMARY

Submitter: Nakanishi, Inc.
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JUN 20 2012

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Date Prepared: July 7, 2011 (*Revised June 18, 2012*)

Trade Name: Ti-Max X450

Common Name: High Speed Air Turbine Handpiece

Classification Name: EFB 872.4200 Handpiece, Air-Powered, Dental

Predicate Device: K952927 - Palisades Dental, Impact Air 45 Handpiece
K101717 - Aerobine, Inc., Air Powered Dental Handpiece [Karam45, Dexor45]

Device Description: The Ti-Max X450 air-powered high-speed dental handpiece capable of reaching rotational speeds of 380,000 to 450,000 revolutions per minute. The device includes non-optic, fiber-optic, and LED models. All models have a 45 degree back angle. Models are available to connect directly to the couplings of specific brands.

Statement of Intended Use: The Ti-Max X450 is an air-powered dental handpiece with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used.

The Ti-Max X450 is intended for use with a friction grip bur that conforms to ISO 1797-1 standard. Recommended supply air pressure is between 0.22 and 0.30 MPa, which results in high-speed bur rotation (approximately 380,000 to 450,000 RPM).

Summary of Technological Characteristics: The Ti-Max X450 is capable of achieving high-speed rotation of 380,000 to 450,000 revolutions per minute when provided with a supply air pressure of 0.22 to 0.30 MPa (32 – 44 psi). This provides a torque of at least 0.09Ncm, while generating a noise level of 80dBA or less. The Ti-Max X450 has a 45 degree back angle. Also available are models with fiber optic or LED lighting. All models include a water jet that is directed to the bur point.

The Ti-Max X450 has a one-touch quick connect coupling system. The Ti-Max X450 can connect directly to the dental unit, or a swivel adapter can be used. Direct connection can be made with 4- and 5-hole connections that meet ISO 9168 specifications. A swivel adapter is connected between the handpiece and hose in the case of 4-, 3-, and 2-hole connections, also in compliance with ISO 9168, type 2. In addition, the Ti-Max X450 has models available that are designed to connect directly to the couplings of other brands.

Performance
Testing:

The Ti-Max X450 was developed and is produced under consideration of all applicable technical standards, internal specifications, and FDA guidance documents. The product's conformance with applicable international and internal standards was verified in the course of bench testing.

Conclusion:

Nakanishi considers the *Ti-Max X450* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design, and established medical use, and demonstrates that the Ti-Max X450 is substantially equivalent to the declared predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JUN 20 2012

Nakanishi, Incorporated
C/O Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

Re: K112024
Trade/Device Name: Ti-Max X450
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 4, 2012
Received: June 12, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

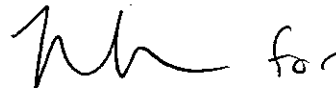
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Ti-Max X450

Indications for Use:

The Ti-Max X450 is an air-powered dental handpiece with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used.

The Ti-Max X450 is intended for use with a friction grip bur that conforms to ISO 1797-1 standard. Recommended supply air pressure is between 0.22 and 0.30 MPa, which results in high-speed bur rotation (approximately 380,000 to 450,000 RPM).

Prescription Use X
(21 CFR 801 Subpart D)

AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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